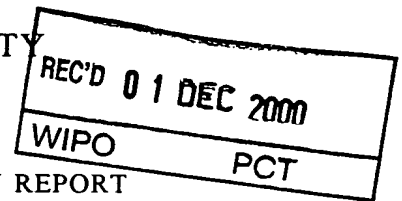


PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



| | | |
|--|---|--|
| Applicant's or agent's file reference 141-201 PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US99/19847 | International filing date (day/month/year) 27 AUGUST 1999 | Priority date (day/month/year) 28 AUGUST 1998 |
| International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet. | | |
| Applicant ANDRX PHARMACEUTICALS, INC. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 20 MARCH 2000 | Date of completion of this report 06 NOVEMBER 2000 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer <i>Susan Tran</i> SUSAN TRAN |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-1235 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19847

I. Basis of the report

1. With regard to the **elements** of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1-17 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____
- ☒ the claims:
pages 18-20 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____
- ☒ the drawings:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____
- ☒ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19847

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>9-11</u> | YES |
| | Claims <u>1-8</u> | NO |
| Inventive Step (IS) | Claims <u>none</u> | YES |
| | Claims <u>1-11</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-11</u> | YES |
| | Claims <u>none</u> | NO |

2. citations and explanations (Rule 70.7)

Claims 1-11 lack an inventive step under PCT Article 33(3) as being obvious over Lovgren et al. in view of Kim. Lovgren et al. teaches a pharmaceutical preparation of omeprazole for oral use. Omeprazole is mixed with inert core comprising alkaline agent in a pellets, tablets, or capsules form and an enteric coating layer. The enteric coating comprising hydroxypropyl methylcellulose phthalate and talc. Lovgren et al. does not teach the claimed lysine or arginine agent, and sodium lauryl sulfate. Kim teaches a pharmaceutical composition of omeprazole comprising lysine or arginine as a stabilizer agent, and sodium lauryl sulfate. Thus it would have been obvious to one of ordinary skill in this art at the time this invention was made to make the Lovgren et al. omeprazole composition using arginine or lysine as the stabilizer in view of the teaching of Kim. One reason for this modification would be to obtain a stable pharmaceutical preparation containing omeprazole for oral use.

----- NEW CITATIONS -----
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19847

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 9/14, 9/16, 9/22, 9/24, 9/30, 9/36, 9/42; A01N 37/00, 37/12 and US Cl.: 424/468, 471, 475, 476, 479, 480, 488, 489, 490, 494, 495; 514/557, 564

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C. 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|---|---|
| Date of mailing (day/month/year) 23 May 2000 (23.05.00) | |
| International application No. PCT/US99/19847 | Applicant's or agent's file reference 141-201 PCT |
| International filing date (day/month/year) 27 August 1999 (27.08.99) | Priority date (day/month/year) 28 August 1998 (28.08.98) |
| Applicant CHEN, Chih-Ming et al | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

20 March 2000 (20.03.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 | Authorized officer S. Mafla Telephone No.: (41-22) 338.83.38 |
|---|--|